Complete Summary

GUIDELINE TITLE

Cervical cancer screening for women who attend STD clinics or have a history of STDs. Sexually transmitted diseases treatment guidelines 2006.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Cervical cancer screening for women who attend STD clinics or have history of STDs. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):67-9. [222 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Cervical cancer screening for women who attend STD clinics or have a history of STDs. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):57-9.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cervical cancer

GUIDELINE CATEGORY

Diagnosis
Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Preventive Medicine

INTENDED USERS

Health Care Providers
Managed Care Organizations
Physicians

GUIDELINE OBJECTIVE(S)

- To update the Sexually Transmitted Diseases Treatment Guidelines 2002 (*MMWR 2002;51[No. RR-6]*)
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)

TARGET POPULATION

Women who attend sexually transmitted disease (STD) clinics or who have a history of STDs

INTERVENTIONS AND PRACTICES CONSIDERED

1. Papanicolaou (Pap) test
2. Follow-up care
3. Colposcopy
4. Directed biopsy
5. Testing for human papillomavirus (HPV) deoxyribonucleic acid (DNA)
6. Special considerations for pregnant women and women infected with HIV

MAJOR OUTCOMES CONSIDERED

- Incidence of cervical cancer
- Prevalence of precursor lesions for cervical cancer
- Sensitivity of screening tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2004, the Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed evidence (including published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the *Sexually Transmitted Diseases Treatment Guidelines, 2002*. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In April 2005, the Centers for Disease Control and Prevention (CDC) staff members and invited consultants assembled in Atlanta, Georgia, for a 3-day meeting to present the key questions regarding sexually transmitted disease (STD) treatment that emerged from the evidence-based reviews and the information available to answer those questions. When relevant, the questions focused on four principal outcomes of STD therapy for each individual disease: 1) microbiologic cure, 2) alleviation of signs and symptoms, 3) prevention of sequelae, and 4) prevention of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy of

specific regimens) also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and attempted to arrive at answers using the available evidence. In addition, the consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Women with a history of sexually transmitted diseases (STDs) might be at increased risk for cervical cancer, and women attending STD clinics might have other risk factors that place them at even greater risk. Prevalence studies indicate that precursor lesions for cervical cancer occur approximately five times more frequently among women attending STD clinics than among women attending family planning clinics. Cervical cancer screening using the Papanicolaou (Pap) test is an effective, low-cost screening test for preventing invasive cervical cancer. Recommendations for cervical cancer screening intervals vary in the United States, but the American Cancer Society and American College of Obstetricians and Gynecologists guidelines recommend annual screening for women aged 21-30 years and then every 2-3 years for women aged $\geq$30 years if three consecutive annual Pap tests are negative.

Recommendations

During the appointment in which a pelvic examination for STD screening is performed, the health-care provider should inquire about the result of the patient's most recent Pap test and discuss the following information with the patient:

- the purpose and importance of a Pap test
- the need for regularly scheduled Pap tests between aged 21-65 years
- whether a Pap test will be obtained during this clinic visit

- if a Pap test will NOT be obtained during this examination, the names of local providers or referral clinics that can perform Pap tests and adequately follow up results if indicated

If a woman has not had a Pap test during the previous 12 months, a Pap test may be obtained as part of the routine pelvic examination. Health-care providers should be aware that many women frequently equate having a pelvic examination with having a Pap test; they believe that a Pap test was taken when they actually received only a pelvic examination. They might, therefore, over report having had a recent Pap test. Therefore, in STD clinics, having a protocol for conducting cervical cancer screening should be highly encouraged and obtaining a Pap test strongly considered during the routine clinical evaluation of women who do not have clinical-record documentation of a normal Pap test within the preceding 12 months.

A woman might benefit from receiving printed information concerning Pap tests and a report containing a statement that a Pap test was obtained during her clinic visit. If possible, a copy of the Pap test result should be provided to the patient for her records when it becomes available.

Follow-Up

STD clinics offering cervical cancer screening are encouraged to use cytopathology laboratories that report results by using the Bethesda System of classification. (Note: The *Bethesda System for Reporting Cervical/Vaginal Cytologic Results* uses the terms "low-grade SIL" and "high-grade SIL" for abnormal results. Low-grade SIL encompasses cytological changes associated with HPV and mild dysplasia. High-grade SIL includes cytological changes associated with moderate dysplasia, severe dysplasia, and carcinoma in-situ. Cytological results should be distinguished from histological results obtained from biopsy specimens.) If the results of the Pap test are abnormal, follow-up care should be provided according to the *American Society for Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines for Management of Abnormal Cervical Cytology*, or information regarding follow-up care is available at http://www.asccp.org. If resources in STD clinics do not allow follow-up of abnormal results, protocols for referral of women needing follow-up and case management should be in place. Pap tests indicating low- or high-grade squamous intraepithelial lesions (SIL) should always include referral to a clinician who can perform a colposcopic examination of the lower genital tract and, if indicated, colposcopically directed biopsy. For patients with an equivocal Pap test report indicating atypical squamous cells of undetermined significance (ASC-US), three options are available for follow-up management: 1) immediate colposcopy, 2) repeat Pap tests at 6-month intervals for 3 intervals, or 3) an HPV deoxyribonucleic acid (DNA) test. Women with ASC-US may be considered for immediate colposcopy if concerns for patient adherence with recommended follow-up or for other clinical indications are a factor. The presence of high grade histological changes after ASC-US Pap test reports usually is <10%.

If repeat Pap tests are used to follow ASC-US results, a test should be performed every 6 months until 3 negative results are noted before the women returns to cervical cancer screening at a normal interval for age. If subsequent Pap tests demonstrate progression to SIL, follow-up should be conducted according to

ASCCP Consensus Guidelines (i.e., frequent colposcopy and directed cervical biopsy). If specific infections other than HPV are identified, the patient might need to have a repeat Pap test after appropriate treatment for those infections. In the majority of instances, even in the presence of some severe infections, Pap tests will be reported as satisfactory for evaluation, so they may be read and final reports produced without the necessity to treat and repeat the Pap test. When repeating the Pap test is necessary because of an unsatisfactory for interpretation report, the repeat test must be interpreted by the laboratory as satisfactory and also be negative before returning the woman to Pap tests at regularly scheduled intervals.

A third strategy for managing patients with ASC-US Pap test results involves testing for HPV DNA. Whereas conducting HPV testing in some STD clinics might not be possible or appropriate because of inadequate resources, such testing might be appropriate in other public health clinic settings. Only one Food and Drug Administration (FDA)-cleared test exists, the Digene Hybrid Capture II. The HPV DNA test may be performed by 1) co-collecting a specimen; 2) using a supplied swab at the time of the Pap test, if conventional cytology is used; 3) reflex testing, if liquid-based cytology is used and enough residual material is available in the cytology test vial; or 4) scheduling a separate follow-up appointment when the Pap test report results are known. If the high-risk HPV DNA test is positive, women are referred immediately for colposcopy, and if indicated, directed cervical biopsy. Because many public health clinics, including the majority of STD clinics, cannot provide clinical follow-up of abnormal Pap tests, women with Pap tests demonstrating low or high grade SIL or ASC-US usually need a referral to other local health-care providers or clinics for colposcopy and biopsy. Clinics and health-care providers who offer Pap test screening services but cannot provide appropriate colposcopic follow-up of abnormal Pap tests should arrange referral to health-care facilities in which 1) a patient will be promptly evaluated and treated and 2) the results of the evaluation will be reported to the referring clinic or health-care provider. Clinics and health-care providers should develop protocols that identify women who miss follow-up appointments so that these women can be located and scheduled for needed studies and management, and they should reevaluate such protocols routinely. Pap test results, type and location of follow-up appointments, and results of follow-up appointments should be clearly documented in the clinic record. The establishment of colposcopy and biopsy services in local health departments, especially in circumstances in which referrals are difficult and follow-up is unlikely, should be considered if resources are available.

Other Management Considerations

Other considerations in performing Pap tests include the following:

- The Pap test should not be considered a screening test for STDs.
- All women, regardless of sexual orientation (heterosexual women and those who identify themselves as lesbian or bisexual), should be considered for cervical cancer screening in an STD clinic setting.
- If a woman is menstruating, a Pap test should be postponed, and the woman should be advised to have a Pap test at the earliest opportunity.

- The presence of a mucopurulent discharge should not delay the Pap test. The test can be performed after careful removal of the discharge with a saline-soaked cotton swab.
- Women who have external genital warts do not need Pap tests more frequently than women who do not have warts, unless otherwise indicated.
- The sequence of Pap testing in relation to collection of other cervicovaginal specimens does not appear to influence Pap test results or their interpretation. Therefore, when other cultures or specimens are collected for STD diagnoses, the Pap test can be obtained last.
- Women who have had a total hysterectomy do not require a routine Pap test unless the hysterectomy was performed because of cervical cancer or its precursor lesions. In these situations, women should be advised to continue follow-up with the physician(s) who provided health care at the time of the hysterectomy, if possible. If the cervix remains after a hysterectomy, a woman should receive regularly scheduled Pap tests.
- Health-care providers who receive basic retraining on Pap test collection and clinics that use simple quality assurance measures obtain fewer unsatisfactory tests. The use of cytobrushes and brooms also improves the number of satisfactory Pap tests.
- Whereas evidence supports the option of HPV testing for the triage of women with ASC-US Pap test reports, this option might not be appropriate in an STD clinic because of limited resources. Studies to define the cost-effectiveness of HPV testing for the triage of women with ASC-US Pap tests are ongoing. The HPV test strategy that might be most cost-effective is the collection of a cervical swab placed in liquid media (i.e., liquid-based cytology or collection of a separate swab stored in HPV DNA transport media) during the initial visit when a Pap test is collected. When the Pap test report is available, an HPV DNA test can be performed on the residual material, if indicated, without the patient needing another clinic visit.
- Liquid-based cytology is an alternative to conventional Pap tests; it has a higher sensitivity for detection of SIL and can facilitate HPV testing in women with ASC-US. However, liquid-based cytology has a lower specificity, resulting in more false-positive tests and, therefore, more administrative and patient-related costs, which could reduce the cost-effectiveness of cervical cancer screening and increase the risk of patient harm because of unnecessary follow-up tests.

Special Considerations

Pregnancy

Pregnant women should have a Pap test as part of routine prenatal care. A cytobrush and an Ayers spatula might be used for obtaining Pap tests in pregnant women.

HIV Infection

Several studies have documented an increased prevalence of SIL in HIV-infected women. The following recommendations for Pap test screening among HIV-infected women are consistent with other guidelines published by the U.S. Department of Health and Human Services and are based partially on the opinions

of professionals knowledgeable about the care and management of cervical cancer and HIV infection in women.

After obtaining a complete history of previous cervical disease, HIV-infected women should be provided a comprehensive gynecologic examination, including a pelvic examination and Pap test, as part of their initial evaluation. A Pap test should be obtained twice in the first year after diagnosis of HIV infection and, if the results are normal, annually thereafter. If the results of the Pap test are abnormal, care should be provided according to the ASCCP Consensus Guidelines for Management of Abnormal Cervical Cytology. Women with cytological reports of ASC-US, low or high-grade SIL or squamous cell carcinoma, regardless of CD4+ count or antiretroviral treatment status, should undergo colposcopy and directed biopsy. Colposcopy and biopsy are not indicated in HIV-positive women with negative Pap test reports.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2006 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased morbidity and mortality from cervical cancer due to early detection and treatment

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). The recommendations are applicable to

various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities.
- These recommendations are meant to serve as a source of clinical guidance: health-care providers should always consider the individual clinical circumstances of each person in the context of local disease prevalence. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in STD/human immunodeficiency virus (HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Cervical cancer screening for women who attend STD clinics or have history of STDs. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):67-9. [222 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1993 (revised 2006 Aug 4)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of persons who have sexually transmitted diseases (STDs) were developed by CDC after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta, Georgia, during April 19–21, 2005.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Cervical cancer screening for women who attend STD clinics or have a history of STDs. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):57-9.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through Annals of Internal Medicine Online.
- The CDC Sexually Transmitted Diseases Treatment Guidelines 2004 for PDA or Palm OS. Available from the CDC National Prevention Information Network (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 5, 2002. This summary was updated by ECRI on October 13, 2006.

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